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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,611	10/06/2000	Gregory Coia	674537-2002	3929

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	19

DATE MAILED: 01/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/623,611	COIA ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *26 April 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1,5,18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology 1600.

2. Claims *1-33* are pending and being acted upon presently.

Sequence Compliance

3. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Drawings

4. The proposed drawing corrections, filed on 4/26/02, have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

5. In addition, a review of the original drawings, filed 10/6/00, has been made by the Draftsman to assist Applicant in the preparation of replacement drawings. Please see the attached PTO 948.

6. Applicant is reminded to amend the Brief Description of the Drawings to reflect the numbering used in the Figures and to describe each individual panel.

For example, "Figure 2:" should read -- Figures 2A-2B: --. In addition, a description should be provided for each panel.

Appropriate correction is required.

Election/Restrictions

7. Applicant's election with traverse of Group I with a species election of CTLA4 in Paper No. 17 is acknowledged. The traversal is on the ground that unity of invention exists because the instant binding moiety is not derived from an antibody.

Applicant's argument is found convincing in part. Upon consideration of Applicant's arguments and review of the claims, the previous Requirement is hereby VACATED.
A new Restriction Requirement follows.

8. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

9. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-21, 28 and 33, drawn to a binding moiety wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is CTLA-4.

Group II, claims 1-11, 13-21, 28 and 33, drawn to a binding moiety wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is CD28.

Group III, claims 1-11, 13-21, 28 and 33, drawn to a binding moiety wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is ICOS.

Group IV, claims 22-27, drawn to a polynucleotide encoding a binding moiety, vectors and host cells comprising, and methods of producing the binding moiety by culturing said host cells, wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is CTLA-4.

Group V, claims 22-27, drawn to a polynucleotide encoding a binding moiety, vectors and host cells comprising, and methods of producing the binding moiety by culturing said host cells, wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is CD28.

Group VI, claims 22-27, drawn to a polynucleotide encoding a binding moiety, vectors and host cells comprising, and methods of producing the binding moiety by culturing said host cells, wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is ICOS.

Group VII, claim 29, drawn to a method of treating by administering a binding moiety wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is CTLA-4.

Group VIII, claim 29, drawn to a method of treating by administering a binding moiety wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is CD28.

Group IX, claim 29, drawn to a method of treating by administering a binding moiety wherein the at least one monomeric V-like domain is derived from a non-antibody ligand that is ICOS.

Group X, claims 30-32, drawn to a method of selecting a binding moiety.

Claim 1 links inventions I, II and III. Claim 22 links inventions IV, V and VI. Claim 29 links inventions VII, VIII and IX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim for the elected invention. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claim are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

10. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of the Groups is considered to be a binding moiety comprising at least one monomeric V-like domain derived (VLD) from a non-antibody ligand, the at least one monomeric VLD being characterized in that the at least one CDR loop structure or part thereof is modified or replaced such that the solubility of the modified VLD is improved when compared with the unmodified VLD.

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Peach et al. (J. Exp. Med. December 1994; 180:2049-2058, IDS #AE, see entire document).

Peach et al. teach chimeric molecules in which complementarity determining regions (CDRs) of CD28 and CTLA4 have been exchanged (see entire document, especially Table 2). Both CTLA4 and CD28 are T cell surface proteins that are non-antibody ligands comprising at least one monomeric V-like domain. Peach et al. show in Figure 4 that chimeric proteins HS10, HS11, HS12 and HS13 each exist in monomeric form.

Although Peach et al. are silent with respect to the effect of these changes in the CDR loop structures on solubility, Peach et al. also show in Figure 4 that chimeric proteins HS10, HS11, HS12 and HS13 each exist in monomeric form at a greater frequency than do either CD28 or CTLA4. Thus Figure 4 provides objective evidence that at least the chimeric proteins HS10, HS11, HS12 and HS13 have improved solubility when compared with the unmodified VLDs of CD28 and CTLA4.

The Examiner acknowledges that the chimeric proteins are fusion proteins. However, the "comprising" language of the claims encompasses fusion proteins. In addition, the chimeric proteins of Peach et al. each are a "binding moiety" since they bind monoclonal antibodies to CD28 (e.g., page 2052, bridging paragraph).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

11. This application contains claims directed to the following patentably distinct species of the claimed inventions:

If one of Groups I-III is elected, Applicant is required to elect a specific embodiment which replaces the CDR loop structure from among those recited in claim 14 or claims 16 and 17 (e.g. replacement with a binding determinant that is somatostatin, or, replacement with one or more CDR loop structures from the human antibody V86).

These species are distinct because each product differs in its structure and physiochemical properties; thus each represents patentably distinct subject matter. Currently, claims13 and 15 are generic.

Applicant is required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
January 2, 2003

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
1/2/03